



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,806	09/28/1999	DENNIS MURPHY	DIVER1120-1	3254

27194 7590 07/23/2004

HOWREY SIMON ARNOLD & WHITE, LLP
C/O M.P. DROSOS, DIRECTOR OF IP ADMINISTRATION
2941 FAIRVIEW PK
BOX 7
FALLS CHURCH, VA 22042

EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1652

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/407,806	Applicant(s) MURPHY ET AL.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 14, 17-25, 27-30, 34, 36, 37, 42, 43, 46-50 and 57-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 14, 17-25, 27-30, 34, 36, 37, 42, 43, 46-50 and 57-69 is/are rejected.
- 7) ☒ Claim(s) 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, 46-50, 57-70 are pending.
- [2] Applicants' amendment to the claims, filed April 16, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed April 16, 2004, is acknowledged.
- [4] Receipt of a substitute Figure 1, filed April 16, 2004, is acknowledged.
- [5] Receipt of a declaration, filed April 16, 2004, under CFR 37 1.132 is acknowledged. The content of the declaration has been fully considered.
- [6] Receipt of a terminal disclaimer, filed April 16, 2004, is acknowledged.
- [7] Applicants' arguments filed April 16, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [8] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.
- [9] It is noted that, in the response filed April 16, 2004, applicants request an interview with the examiner. The examiner complied with applicants' request and a telephonic interview was conducted on July 14, 2004. An interview summary is attached to the instant Office action.

Specification/Informalities

[9] The objection to the specification under 35 USC 132 as set forth in item [9] of the Office action mailed November 17, 2003, is maintained. In summary, the objection is based upon an amendment to the sequence listing and Figure 1, which incorporates new matter into the specification.

[10] RESPONSE TO ARGUMENTS: Applicants state that upon re-sequencing of plasmid 18GC, three nucleotide discrepancies have been noted, which did not alter the encoded sequence of SEQ ID NO:4 (see page 12 of the amendment filed April 23, 2003). Applicants state plasmid 18GC has been deposited and accepted with the ATCC and has been designated PTA-4654. Applicants state this information was incorporated into the specification and a substitute sequence listing reflecting the re-sequenced nucleic acid was added in the previous response (amendment filed April 23, 2003). Applicants argue the deposited nucleic acid described the sequence sufficient to meet the written description requirement of 35 USC 112, first paragraph, citing Enzo Biochem, Inc. v. Gen-Probe Inc., 63 USPQ2d 1609 (Fed. Cir. 2002). Applicants argue that the addition of information designating a depository, accession number, and deposit date of the deposited biological material in the ATCC after the filing date does not violate the prohibition against new matter, citing MPEP 2163, 2406.01, and In re Lundak, 773 227 USPQ 90 (Fed. Cir. 1985). Applicants' argument is not found persuasive.

There is no dispute that addition of depository information following the filing date of the application does not violate the prohibition against new matter.

Accordingly, the objection is not based upon applicants' amendment to the specification to insert the depository information. As stated above, the objection is based upon applicants' amendment to the sequence listing and Figure 1, based upon re-sequencing of plasmid 18GC. Applicants assert the deposit was made on September 10, 2002, which is after the effective filing date of the instant application. MPEP 2163, addressing sequencing errors and correction thereof based upon deposited biological material, states, "[d]eposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed."

It is further noted that nowhere in the instant application is plasmid 18GC identified. Applicants assert plasmid 18GC is identified in the specification at page 4, lines 20-22. Page 4, lines 20-22 of the specification reads as follows: "[a]ccordingly, the polynucleotides and enzymes thereby are identified by the organism from which they were isolated, and are sometimes hereinafter referred to as "AEDII12R- α -gal-18GC" (Figure 1 and SEQ ID NOS:3 and 4)." Lines 20-22 of page 4 of the specification make no reference to a *plasmid* designated as "18GC." At best this disclosure provides a designation for the polynucleotide of SEQ ID NO:3 and/or the polypeptide of SEQ ID NO:4. Thus, the amendment to the sequence listing and Figure 1 is not proper and constitutes new matter to the specification. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

[11] In view of applicants' amendment to the claims, the objections to claims 1 and 27 as set forth in items [10] and [11] of the Office action mailed November 17, 2003, are withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

[12] In view of the amendment to the claims, the rejection of claims 8, 20, and 28 under 35 USC 112, second paragraph, as set forth in item [12] of the Office action mailed November 17, 2003, is withdrawn.

[13] The rejection of claims 2-4, 17-19, 21-23, and 61 as being confusing in the recitation of "comprises" is maintained for the reasons of record as set forth in item [12] part [a] of the Office action mailed November 17, 2003 and for the reasons stated below.

[14] RESPONSE TO ARGUMENTS: Applicants attempt to provide clarification of the term "comprises" by asserting this term is meant to be interpreted as an "open-ended term." Applicants' remarks are not found persuasive.

The term remains unclear and confusing. As written, it appears that the term is to be interpreted as "is," e.g., "the polynucleotide is a DNA" in claim 2. However, applicants assertion that the term is meant to be "open-ended" is not sufficient to clarify the meaning of the term. In view of applicants' "clarification," it is unclear as to whether this term is to be interpreted as meaning that, e.g., part (a) or (b) of the polynucleotide of claim 1 is a DNA, or if it is meant to be interpreted as meaning that, in addition to part (a) or (b), which may or may not be a DNA, the polynucleotide comprises some other undefined and/or

Art Unit: 1652

undisclosed DNA. As such, it is suggested that applicants further clarify the meaning of the term.

[15] Claims 1-3, 5-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, and 57-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 1 (claims 2-3, 6-9, 13-14, 17-23, 29-30, 36-37, 42-43, 57-62, and 64-67 dependent therefrom), 5, 24 (claims 25, 27-30, 36-37, 42-43, and 62 dependent therefrom), 34, and 63 (claims 68-69 dependent therefrom) are indefinite in the recitation of “a sequence complementary to the sequence of (a)” as it is unclear as to whether the complementary sequences are completely or partially complementary to the sequence of (a). The specification fails to define the term “complementary” and suggests that such complements encompass partial complements of a nucleic acid (see particularly page 8, bottom). It is suggested that applicants clarify the meaning of the claims, by for example, amending the claims to recite “completely” or “fully” before “complementary.” In the interest of advancing prosecution, the claims have been interpreted as reciting “completely complementary.”

[b] Claims 29-30 (claims 36, 37, and 62 dependent therefrom) are indefinite in the recitation of “hybridization” as this term is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions will not necessarily hybridize under different conditions and thus, the scope of claimed probes is unclear.

Claim Rejections - 35 USC § 112, First Paragraph

[16] Claims 1-3, 5-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, 46-50, 57-62, and 64-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of polynucleotides comprising variants and fragments of a polynucleotide encoding SEQ ID NO:4. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of claimed polynucleotides, i.e., SEQ ID NO:3 encoding the polypeptide of SEQ ID

Art Unit: 1652

NO:4. The specification fails to describe any additional representative species of the claimed genus of polynucleotides. While MPEP § 2163 acknowledges that in certain situations “one species adequately supports a genus”, it is also acknowledges that “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus”. In the instant case, the recited genus encompasses species having widely variant structures and/or functions – including mutants, allelic variants, and/or genomic DNA. As such, the disclosure of the single representative species, i.e., SEQ ID NO:3, is insufficient to be representative of the attributes and features of *all* species encompassed by the recited genus. Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[17] RESPONSE TO ARGUMENTS: Applicants argue a single representative species can adequately describe a claimed genus of nucleic acids, when the genus is defined in terms of hybridization under specific conditions to an exemplary species, the genus encodes an active polypeptide, and procedures for identifying the species encompassed by the genus were conventional in the art at the time of the invention. Applicants cite the declaration of Dr. Short (hereafter referred to as the “Short Declaration”) as allegedly demonstrating that methods for screening for nucleic acids encompassed by the genus were conventional and routine at the time of the invention and yielded, the successful results of

Art Unit: 1652

which were allegedly predictable. Applicants argue that since the claimed invention “encompassed a predictable art,” a single representative species can sufficiently describe the claimed genus. Applicants’ argument is not found persuasive.

It should be noted that Dr. Jay Short is a concerned party in the prosecution of the instant application.

Regarding the merits of applicants’ arguments, there is no dispute that a single representative species can describe a genus, as is stated in MPEP 2163. Further, there is no dispute that, at the time of the invention, methods of hybridization and methods of enzymatic assay for alpha galactosidase activity were known in the art. However, in this case, the single disclosed representative species fails to represent the entire genus of claimed nucleic acids. It should be noted that, contrary to applicants’ assertion, none of the species of the genus of claimed nucleic acids is limited to those that encode an enzymatically active polypeptide. For example, claims 1 and 24 are drawn to a polynucleotide that merely has sequence identity to or hybridizes to a nucleic acid that encodes a polypeptide having alpha galactosidase activity – there is no recited requirement that the *claimed* polynucleotide encode an enzymatically active polypeptide. The genus of polynucleotides of claims 1 and 24, while limited in structure by their relatedness to other nucleic acids, are unlimited with respect to function. Thus, the genus of nucleic acids of claims 1 and 24 are widely variant with respect to their function(s). Similarly, the genus of nucleic acids of claim 34 are widely variant with respect to their structures as there is no requirement that the “12

Art Unit: 1652

contiguous nucleotides of a polynucleotide encoding SEQ ID NO:4" be a subsequence of SEQ ID NO:4 and widely variant with respect to their function(s) as the claimed genus can amplify any alpha-galactosidase encoding nucleic acid within the scope of the claim. MPEP § 2163 states when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. However, in this case, the specification discloses only a single representative species of the genus of claimed polynucleotides, i.e., SEQ ID NO:3 encoding the polypeptide of SEQ ID NO:4, which is insufficient to reflect the wide variation within the genus. Due to the wide variation in the structures and/or functions of the members of the genus, one of skill in the art at the time of the invention was not able to "visualize or recognize the identity of the members of the genus" as required by the holding of University of California v. Eli Lilly and Co. 43 USPQ2d 1398 the specification fails to describe the genus of claimed nucleic acids.

[18] The scope of enablement rejection of claims 1-3, 5-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, 46-50, 57-62, and 64-67 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [14] of the Office action mailed November 17, 2003 and for the reasons stated below. The specification, while being enabling for a polynucleotide encoding SEQ ID NO:4, does not reasonably provide enablement for *all* polynucleotide variants and/or fragments as encompassed by the claims.

[19] RESPONSE TO ARGUMENTS: Applicants argue the specification is enabling for the full "genus of polypeptides having alpha galactosidase activity."

Art Unit: 1652

Applicants rely on the Short Declaration as supporting applicants' position that: 1) undue experimentation is not required to make and use all nucleic acids encompassed by the claims; 2) no guidance or knowledge of the structure-function relationship of alpha galactosidases is necessary to make and use all nucleic acids encompassed by the claims; 3) methods for identifying and screening nucleic acids encoding alpha galactosidase polypeptides were known and were routine at the time of the invention and whose success was allegedly predictable. Applicants argue that screening of a large number of compositions is irrelevant to an enablement inquiry, citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987). Applicants argue practitioners of the biological sciences recognized the need to screen "numbers of negatives" to find a sample having a desired property and that such screening was routine. Applicants argue the specification discloses that degenerate variants of SEQ ID NO:3 encode SEQ ID NO:4. Applicants' argument is not found persuasive.

It is noted that the claims are not drawn to a "genus of polypeptides" as asserted by applicants (page 18, line 21 of the response), but are instead drawn to nucleic acids. It is also noted that Dr. Jay Short, whose declaration is relied upon by applicants, is a concerned party in the prosecution of the instant application.

Regarding the merits of applicants' arguments, the examiner disagrees with applicants' assertion that "whether large numbers of compositions... .. must be screened... .. is irrelevant to an enablement inquiry" (page 20, lines 2-4 of the

response). The amount of screening required is not irrelevant as it must be determined whether such screening is or is not routine. In this case, undue experimentation is required to make and use all nucleic acids encompassed by the broad scope of the claims, at least for the reasons of record, reiterated herein, and the reasons stated below. The claims are not limited to those nucleic acids encoding polypeptides having alpha-galactosidase activity, and thus, the claims broadly encompass nucleic acids encoding polypeptides having any activity, including nucleic acids that encode non-functional polypeptides and polypeptides having activity other than alpha-galactosidase activity. Regarding those nucleic acids broadly encompassed by the claims that have alpha-galactosidase activity, while methods of screening polypeptides for alpha galactosidase activity were known in the art at the time of the invention, it is not routine experimentation to randomly create a VAST number of nucleic acid variants (as encompassed by the instant claims) to test the resulting variants for alpha galactosidase activity. Instead, a skilled artisan would require some knowledge or guidance as to which structural elements (i.e., encoding nucleotides or encoded amino acids) correlate with alpha-galactosidase activity within the polypeptide of SEQ ID NO:4 before generating and testing variants for the desired activity. The specification is silent as to which nucleotides can be modified by insertion, deletion, addition, or substitution to create variants of SEQ ID NO:3 that maintain alpha galactosidase activity. The prior art clearly indicates the high level of unpredictability of the effect(s) of altering even a single amino acid within an enzyme as evidenced by the objective references of Branden et al.

Art Unit: 1652

and Witkowski et al., whose teachings are undisputed by applicants. Thus, while the specification may enable one of skill to use the claimed nucleic acids, the specification certainly does not enable a skilled artisan to make all nucleic acids encompassed by the claims. Further, for those nucleic acids encompassed by the claims that encode non-functional polypeptides or polypeptides having activity other than alpha galactosidase enzyme activity, it is noted that the specification provides zero guidance for making and using nucleic acids that do not encode alpha galactosidase activity and further fails to provide guidance for using such nucleic acids. As such, the specification fails to enable the full scope of claimed nucleic acids.

Applicants argue University of Rochester v. G.D. Searle & Co. Inc., F. Supp. 2d 216 (W.D.N.Y., 2003) is not analogous to the instant case because: 1) the claimed nucleic acids are described by structure, physico-chemical properties, and function; and 2) University of Rochester involved claims to a chemical compound, wherein the holding of University of Rochester supports the argument that a single nucleic acid species may support a claim to a genus of complementary nucleic acid molecules. Applicants' argument is not found persuasive.

Initially, it should also be noted that the claimed nucleic acids are not limited to those that encode polypeptides having alpha galactosidase activity, but are instead essentially unlimited with respect to the function of the corresponding encoded polypeptide.

Applicants have failed to distinguish the instant case from that of University of Rochester. Regarding applicants' first asserted distinction, while it is acknowledged that the claims recite a structural feature for the nucleic acids, it is noted that the specification (with the exception of degenerate variants, to which the claims are not so limited) fails to disclose even a single working example of a variant of SEQ ID NO:3 encoding a polypeptide having alpha galactosidase activity. Applicants argue that methods for identifying such variants were well known in the art, relying on the Short Declaration. However (with the exception of degenerate variants), *not even a single variant has been disclosed* and, contrary to applicants' assertion, there is no way to predict the effects of even a single amino acid change within a protein's amino acid sequence (as evidenced by Branden et al. and Witkowski et al.) Without additional guidance, the suggestion that the variants can be isolated by screening methods that were known in the art at the time of the invention would suggest that the specification is no more than a starting point for additional research for those of skill in the art to experiment in order to generate the entire scope of recited nucleic acids. Thus, University of Rochester is analogous to the instant case.

Regarding applicants' second asserted distinction, It is noted that applicants' remarks addressing University of Rochester are directed to the written description rejection and not the issue at hand, i.e., whether the specification enables the full scope of claimed nucleic acids. However, in order to be fully responsive to applicants' argument, it is noted that there is no dispute that, upon knowing the specific sequence of a single strand of a nucleic acid that one can

Art Unit: 1652

predict the corresponding complementary strand according to Watson-Crick base pairing. However, the claims are not so limited to a specific sequence such that one of skill can envision the "precise sequence" of a complement thereof. In this case, the claims broadly encompass a vast number of variants of SEQ ID NO:3 and a nucleic acid encoding SEQ ID NO:4, the specification provides insufficient guidance as to how one would make and/or use the full scope of claimed nucleic acids, there is a high level of unpredictability in making the variants of SEQ ID NO:3/a nucleic acid encoding SEQ ID NO:4 with an expectation of those variants maintaining alpha-galactosidase activity, and the amount of experimentation required to make the vast number of variants is not routine. In this case, the evidence, when taken as a whole, indicates that undue experimentation is required to make and use the full scope of claimed nucleic acids.

Double Patenting

[20] In view of the submission of a terminal disclaimer, the provisional double patenting rejections of claims 1-9, 13-14, 17-25, 27-30, 34, 36-27, and 42-67, as set forth in items [15], [16], and [17] of the Office action mailed November 17, 2003, are withdrawn.

[21] Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 co-pending Application No. 10/112,357 (hereafter referred to as the "'357 Application"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim

Art Unit: 1652

is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application and the claims of the '357 Application are both directed to a process or method of making a polypeptide. The claims differ in that the nucleic acids encoding the polypeptides produced by the methods are not identical. The specification of the '357 Application supports a nucleic acid encompassed by claim 8 of the instant application (see, e.g., page 36, paragraph [0127] of the '357 Application). The claims of the instant application cannot be considered to be patentably distinct over the claims of the '357 Application when there is a specifically disclosed embodiment in the '357 Application that supports that claim, i.e., producing a polypeptide encoded by SEQ ID NO:3. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 29 of the '357 Application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

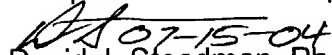
Conclusion

[22] Status of the claims:

Art Unit: 1652

- Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, 46-50, 57-70 are pending.
- Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, 42-43, 46-50, 57-69 are rejected.
- Claim 70 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

 07-15-04

David J. Steadman, Ph.D.

Patent Examiner

Art Unit 1652